

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diprobase Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipients include: Chlorocresol and Cetostearyl alcohol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the UK:
A smooth, uniform white cream.

4 CLINICAL PARTICULARS

As per PA1410/076/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/076/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Macrogol cetostearyl ether
Cetostearyl alcohol
Liquid paraffin
White soft paraffin
Phosphoric acid
Sodium dihydrogen phosphate
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

50g tube with a plastic cap, presented in an over-labelled carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

Any unused product or waste material should be disposed of in accordance with the local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/182/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd February 2013

10 DATE OF REVISION OF THE TEXT

April 2015